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NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			ROANE, AARON F	
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			3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/027,134	Applicant(s) WELLMAN ET AL.	
	Examiner Aaron Roane	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-13, 15 and 16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 8, 10, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in further view of Tetzlaff et al. (USPN 6,277,117 B1).

Regarding claims 1, 2, 7 and 13, Yamanashi et al. disclose a bipolar forceps device having a sharp pointed tissue-piercing distal tip, first and second members having non-destructive tissue-contacting conductive surfaces (tissue grasping surfaces of the jaw members (40 and 38)), wherein the first and second members are pivotably movable with respect to each other and connected to a power source, see col. 2-5 and figures 2, 3 and especially 4. Yamanashi et al. fail to explicitly show the pivot connected the first and second members and do not show a close up of the first and second conductive elements connected to the first and second members respectively. Additionally, Yamanashi et al.

fail to disclose that the first and second tissue contacting conductive elements are substantially circular in shape extending along the length thereof. It is well known in the art to provide the first and second members disclosed by Yamanashi et al. with a pivotable connection in order to facilitate the opening and closing of the members with respect to each other and to place a first electrically conductive element on the first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces. As an illustrative example, Dorn discloses an electrosurgical forceps device and teach providing a pivot pin (72) between the first (16) and second (14) members in order to provide the members with opening and closing capabilities with respect to each other and also teach placing a first electrically conductive element (38) on the first member and a second electrically conductive element (36) on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces, see col. 4-7 and figures 1-3. Also it is well known in the art to provide forceps jaws with substantially circular shape extending along the length of the jaws, or curved jaws in order to provide the necessary sealing along a particular desired path. Tetzlaff et al. disclose an electrosurgical forceps device and teach the provision of curved forceps jaws (110 and 120) in order to provide hemostasis along a desired non-linear path, see col. 1-10 and figures 1-3. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al., as is well known in the art and taught by Dorn, to provide a pivot pin between the first and second members in order to provide the members with opening and closing capabilities with

respect to each other and also teach placing a first electrically conductive element on the first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces, and as is well known in the art and further disclosed by Tetzlaff et al., to provide curved forceps jaws in order to provide hemostasis along a desired non-linear path.

Regarding claims 3 and 15, Yamanashi et al. in view of Dorn disclose an actuating member (loop rings of handle) mated to the first and second members and effective to selectively move the members between the open and closed positions, see figure 4 of Yamanashi et al.

Regarding claim 4, Yamanashi et al. in view of Dorn further that first and second members are elongate and each member includes a proximal end mated to the actuating member, and a distal portion having the conductive element disposed thereon.

Regarding claim 8, Yamanashi et al. in view of Dorn further that one of the first and second conductive elements is an active energy transmitting electrode, and the other one of the first and second conductive elements is a return electrode (this is inherent in a bipolar device).

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Regarding claim 10, Yamanashi et al. in view of Dorn further disclose that an insulative coating (34 and 32) disposed around a portion of at least one of the first and second members, see Dorn figure 2 and col. 5.

Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in still further view of Tetzlaff et al. (USPN 6,277,117 B1) as applied to claim 1 above, and further in view of Nezhat et al. (USPN 6,514,252 B2).

Regarding claim 6, Yamanashi et al. in view of Dorn in still further view of Tetzlaff et al. disclose the claimed invention except for explicitly reciting that the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member. Nezhat et al. disclose a bipolar forceps instrument and teach the use of a large number of alternate electrically conductive jaw surface configuration including one wherein the first conductive element (108) comprises first (100a) and second (100b) electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode (102) extending along the length of the distal portion of the second member and adapted

to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member, see col. 2-5, col. 10, lines 1-36 and figure 9D. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Nezhat et al., to provide an alternate jaw surface configuration wherein the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member.

Regarding claim 16, Yamanashi et al. in view of Dorn in still further view of Tetzlaff et al. in further view of Nezhat et al. disclose the claimed invention, see Nezhat et al. figure 9D.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in still further view of Tetzlaff et al. (USPN 6,277,117 B1) as applied to claim 1 above, and further in view of Swanson et al. (USPN 6,610,055 B1).

Regarding claim 9, Yamanashi et al. in view of Dorn disclose the claimed invention except for explicitly reciting that at least one of the first and second members is

malleable. Swanson et al. disclose an electrosurgical forceps device and teach that “the forceps-like apparatus 150 includes arms 154 and 156 that are pivotably secured to one another by a pin 158 to allow the device to be opened and closed. The proximal portions of the arms 154 and 156 may be formed from rigid or malleable material. The arm distal portions 160 and 162, which are curved and support the tissue coagulation apparatus 152, are preferably formed from malleable material. This allows the arm distal portions 160 and 162 to be re-shaped by the physician as needed for particular procedures and body structures (note the dash lines in FIG. 21), see col. 16, line 63 through col. 17, line 10 and figures 21-25. Arms 154 and 156 are analogous to the first and second members.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Swanson et al., to provide the first and second members in a malleable form in order to be re-shaped by the physician as needed for particular procedures and body structures.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) in still further view of Tetzlaff et al. (USPN 6,277,117 B1) as applied to claim 1 above, and further in view of Chen et al. (USPN 6,102,909).

Regarding claim 12, Yamanashi et al. in view of Dorn in still further view of Tetzlaff et al. disclose the claimed invention except for explicitly reciting that the first and second members are biased in the closed position. It is well known in the art to bias the jaw

members of forceps in order to hold tissue. Chen et al. disclose an electrosurgical instrument and teach providing the instrument with a means to bias the opposing members in an open or closed position depending on the desired effect, see col. 5, lines 3-6 and col. 16, lines 30-39. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Chen et al., to provide the instrument with a means to bias the opposing members in an open or closed position depending on the desired effect.

Claims 1, 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fozard (USPN 2,888,927) in view of Mehl, Sr. (USPN 5,846,252) in further view of Grisoni (US D452,936 S).

Regarding claim 1, Fozard discloses a medical device (11) comprising a first member (distal portion of first 24 ending in 19) having a first non-destructive tissue-contacting conductive element in communication with a source (10) of ablative energy; and a second member (distal portion of second 24 ending in 18) having a second non-destructive tissue-contacting element, the second member being pivotally coupled (22) to the first member and including a distal tissue-piercing tip adapted to be deployed into tissue to allow the first conductive element to be positioned on a first tissue surface and the second conductive element to be positioned on a second tissue surface opposed to the first tissue surface such that ablative energy can be transmitted between the first and second conductive elements, see col. 1-2 and figure 1. Fozard fails to disclose a second

electrically conductive element on the second member because Fozard discloses a monopolar device. Fozard also fails to disclose that the first and second tissue contacting conductive elements are substantially circular in shape extending along the length thereof. It is extremely well known in the art to bipolar capability to monopolar devices in order to obtain higher localized current densities. Mehl, Sr. discloses a medical device similar to that of Fozard (both are electrical tweezers/forceps devices directed to the removal of hair) and teach the use of a first electrically conductive element (24) disposed on the first member (20) and a second electrically conductive element (26) disposed on the first member (22) in order to provide a bipolar configuration, see col. 3 and figures 1 and 2. It is extremely well known in the art to curved tweezer jaws, wherein the jaws are substantially circular in shape extending along the length thereof. Grisoni discloses are precision tweezers and teaches providing the tweezer jaws in a variety of shapes including curved tweezer jaw shape, wherein the jaws are substantially circular in shape extending along the length thereof. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Fozard, as is well known in the art and taught by Mehl, Sr., to use a first electrically conductive element disposed on the first member and a second electrically conductive element disposed on the second member in order to provide a bipolar configuration, and as is well known in the art and further shown by Grisoni, to provide the tweezer jaws in a variety of shapes including curved tweezer jaw shape, wherein the jaws are substantially circular in shape extending along the length thereof.

Regarding claim 3, Fozard further discloses an actuating member (proximal portions of both 24's) mated to the first and second members and effective to selectively move the members between the open and closed positions, see col. 1-2 and figure 1.

Regarding claim 11, Fozard further discloses that the actuating member comprises opposed first and second handles (proximal portions of both 24's), wherein a force applied to bring the first and second handles in contact with each other causes opening of the first and second members, see col. 1-2 and figure 1.

Response to Arguments

Applicant's arguments filed 4/26/2005 have been fully considered but they are not persuasive.

The examiner will address each argument/remark in turn.

Regarding the arguments/remarks of section A1), namely "the combination of references does not teach the claimed invention" beginning on page 2, the last paragraph. Applicant argues that Dorn adds nothing to the Yamanashi et al. reference. Yamanashi does not explicitly disclose/show a pivot pin that couples the jaw members together. The examiner pointed out that

it is extremely well known in the art to one of ordinary skill to provide the jaw members with a pivot and provided Dorn to illustrate this well known point.

Next, Applicant goes on to state that regarding Yamanashi et al., “the distal tips do not include tissue-contacting conductive elements extending therealong, much less conductive elements having a substantially circular shape. Rather, the distal tips are the tissue-contacting conductive elements,” see 2nd paragraph of page 3, lines 3-5. First, the distal tips of Yamanashi define a tissue contacting area, and not simply an individual tissue contacting point. That tissue contacting area of the distal tips is a conductive element and extends therealong. The examiner agrees with Applicant’s assertion that Yamanashi et al. and Dorn do not disclose a substantially circular shape the tissue-contacting conductive element. Tetzlaff et al. disclose an electrosurgical forceps device and teach providing “curved forceps jaws” which are in themselves electrically conductive tissue contacting surfaces having a substantially circular shape extending therealong. It should be noted here, if Applicant wishes to claim tissue-contacting conductive element having a substantially circular cross section extending therealong, wherein said substantially circular cross section is transverse with respect to the longitudinal axis of the jaw members, then Applicant needs to amend the claims in such a way as to make this recitation plain and clear. As it is, Applicant has not explicitly recited a substantially circular cross section as such. Therefore, Applicant’s assertion that the electrodes Tetzlaff et al. “do not have a substantially circular shape, and they do not extend along the length of the jaws” is incorrect.

Turning to argument/remark A2), “the examiner has failed to identify the motivation necessary to combine the references” beginning on page 3, last three lines, Applicant asserts that

“the examiner has also failed to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine the references. In combining references to support an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The teaching or motivation must come from the references, and it cannot be derived from Applicant's teachings.” First, the examiner wishes to thank Applicant for the above remark, because it highlights and illustrates a fault in Applicant argument/remark. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F. 2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). Secondly, the motivation for combining Dorn with Yamanashi et al. is clear, well defined and proper and the examiner will not address it further, the motivation for combining Tetzlaff et al. with Yamanashi et al. and Dorn, is supplied two-fold: 1) it is well known in the art and would be obvious to one of ordinary skill in the art to modify Yamanashi et al. in view of Dorn, to provide curved forceps jaws in order to provide hemostasis along a desired non-linear path, 2) Tetzlaff et al. disclose a wide variety of jaw configurations and teach their alternate use in order to suit a particular purpose, see col. 9 of the Tetzlaff et al. reference.

Next, Applicant's assertion in the 2nd paragraph of page 4 make very little sense due to what the examiner believes is a misprint. Applicant states therein "First, as previously noted, Tetzlaff does not teach non-conductive elements extending along the surface, but rather the device includes electrodes disposed on the distal-most tip of the device. Tetzlaff thus cannot be used to provide hemostasis along a desired non-linear lesion." The examiner believes Applicant meant to state -- First, as previously noted, Yamanashi et al. do not teach conductive elements extending along the surface, but rather the device includes electrodes disposed on the distal-most tip of the device. Tetzlaff thus cannot be used to provide hemostasis along a desired non-linear lesion.-- Yamanashi et al. certainly do disclose forceps jaws having conductive elements extending therealong and suggests that Applicant misunderstands the disclosure of Yamanashi et al. since their disclosure is directed to electroconvergent cautery system in the form of an electrosurgical laproscopic forceps device used for cauterization/coagulation wherein the entire length of 38 and 40 are electrically conductive tissue contacting members. Therefore, Tetzlaff can be used to provide hemostasis along a desired non-linear lesion contrary to Applicant's assertion. Secondly, Applicant states Yamanashi et al. "already provides non-linear jaws having electrodes for use in providing hemostasis, i.e., in coagulating tissue. Figure 2 illustrates an embodiment in which the jaws include a bend formed therein, and the distal-most tip of each jaw is conductive to coagulate/cut tissue. Accordingly, Tetzlaff is merely cumulative and does not provide the necessary motivation to modify Yamanashi." The examiner does not necessarily agree that Yamanashi et al. disclose what Applicant has asserted above. However, the statement that Tetzlaff et al. "is merely cumulative," although the examiner does not concede this point, would seem to weaken Applicant's argument since as it has been pointed out above, the test for

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obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F. 2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). The motivation for combining Dorn with Yamanashi et al. is clear, well defined and proper and the examiner will not address it further, the motivation for combining Tetzlaff et al. with Yamanashi et al. and Dorn, is supplied two-fold: 1) it is well known in the art and would be obvious to one of ordinary skill in the art to modify Yamanashi et al. in view of Dorn, to provide curved forceps jaws in order to provide hemostasis along a desired non-linear path, 2) Tetzlaff et al. disclose a wide variety of jaw configurations and teach their alternate use in order to suit a particular purpose, see col. 9 of the Tetzlaff et al. reference.

Regarding the remainder of the arguments/remarks in this section, namely, section A2), the examiner directs Applicant to some/all of the responses of the examiner mentioned above.

Moving onto the arguments/remarks of section A3), namely, "the references are non-analogous art." Of all the arguments/remarks presented so far, this is the easiest to address. It is well known in the art that coagulation and ablation are interpreted as the same, generally, devices that can coagulate tissue and also ablate tissue. Therefore, generally and more specifically, the prior art does pertain to the problem that Applicant's claimed invention is directed to.

Next, we move onto the arguments/remarks directed to the set of rejections based on Fozard in view of Mehl, Sr. in further view of Grisoni. Applicant asserts that “the combination of references does not teach the claimed invention.” Again, as broadly defined by the claim language the claimed invention is disclosed by the combination of Fozard in view of Mehl, Sr. in further view of Grisoni, with particular attention paid to the tissue-contacting conductive elements extending therealong having a substantially circular shape. Again, the examiner suggests that Applicant provide claim language which distinguishes the claimed invention over the prior art.

Applicant asserts in section B2) that “the references are non-analogous art.” Applicant’s invention is directed to ablation of tissue, whereas the prior art is directed to hair removal. At first glance one might agree with Applicant. However, upon further review and consideration, the prior art it also directed to the application of electrical energy to a person through forceps/tweezers (and is capable of ablating tissue) and therefore is analogous because both the claimed invention and the prior art are broadly directed to the application of electrical energy to a patient/person.

After reviewing and fully considering Applicant’s arguments/remarks, the examiner believes that the prior art and the combinations of the prior art are useful and pertinent and that the rejections based on the prior art of record are proper and therefore reaffirmed. Furthermore, the above responses to Applicant’s arguments/remarks fully address and refute these arguments/remarks.

This action is made FINAL.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
July 19, 2005

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER